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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,149	10/20/2003	Miri Seiberg	J&J1886CIP1	6375

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EXAMINER
HUYNH, CARLIC K

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,149	SEIBERG ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *5-8,10-12,14-16,21-24,26-28 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,13,17-20,25 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :17 March 2004, 12 July 2004, 30 August 2004, 23 March 2005, 21 April 2005, 13 July 2006, 17 November 2006, and 16 July 2007.

DETAILED ACTION

Status of the Claims

1. Claims 1-32 are pending in the application, with claims 5-8, 10-12, 14-16, 21-24, 26-28, and 30-32 in response to the restriction requirement submitted on January 17, 2007. Accordingly, claims 1-4, 9, 13, 17-20, 25, and 29 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election with traverse of the claims of Group I, namely claims 1-4, 9, 13, 17-20, 25, and 29, in the reply filed on February 20, 2007 is acknowledged. The traversal is on the ground(s) that the unrelated groups (Groups I-V) are related, "as it is possible to utilize at least some of the elements of the compositions set forth in the different groups in the same composition" and that "the searching of all Groups of claims should not entail a burden".

Applicants' arguments were not found persuasive. The examiner maintains and argues that "the combination as claimed does not require the particulars of the subcombination as claimed because (1) the combinations can require any subcombination such as an anti-viral agent and (2) the subcombination has separate utility such as an anti-inflammatory for pain medication, as an anti-cancer agent for chemotherapy, as an anti-oxidant for anti-aging therapy, and as a sunscreen"; (see MPEP § 806.05(c)). The applicant is reminded that "Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104". See MPEP § 821.04(a).

Regarding Groups II-V, "Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06)". The examiner maintains and argues that "the different inventions II-V are not capable of being used together and they have different designs as Invention II uses an anti-inflammatory agent, Invention III uses an anti-cancer agent, Invention IV uses an anti-oxidant, and Invention V uses a sunscreen". Thus the restriction requirement is still deemed proper and is maintained.

Claims 5-8, 10-12, 14-16, 21-24, 26-28, and 30-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on February 20, 2007.

Because Group I was elected, the election of species was not required.

Accordingly, claims 1-4, 9, 13, 17-20, 25, and 29 are being examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statements submitted on March 17, 2004, July 12, 2004, August 30, 2004, March 23, 2005, April 21, 2005, July13, 2006, November 17, 2006, and July 16, 2007, are acknowledged.

Specification

3. The use of the trademark Iniferine® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 9, 13, 17-20, 25, and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the risk of cutaneous tumor development or ultraviolet radiation-induced skin cancer, does not reasonably provide enablement for preventing cutaneous tumor development or ultraviolet radiation-induced skin cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex*

parte Forman, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to a method of reducing or preventing the risk of cutaneous tumor development or ultraviolet radiation-induced skin cancer in skin cells.

(2). ***State of the Prior Art***:

The skilled artisan would view that the prevention of skin cancer is highly unlikely. In fact, there are no methods to prevent any cancer in the prior art.

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the arts of skin cancer and soy products are extremely high.

(4). ***Predictability of the Art***:

The prevention of an skin cancer or cutaneous tumor is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an

unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass a method of reducing or preventing the risk of cutaneous tumor development or ultraviolet radiation-induced skin cancer in skin cells.

(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to the method of preventing the risk of cutaneous tumor development or ultraviolet radiation-induced skin cancer in skin cells is limited.

The disclosure of the method of reducing the risk of cutaneous tumor development or ultraviolet radiation-induced skin cancer in skin cells is adequate (pages 30-32, Example 4).

(7). ***Working Examples***:

The working examples in the specification show pretreatment with soy milk reduced or eliminated T-T dimers in swine epidermis (page 31, lines 1037-1040). Accordingly, pretreatment with non-denatured soy extracts reduces the UV-induced cellular and DNA damage that are known to be involved in the formation of skin cancer (page 32, lines 1045-1048). Thus, the working examples show how to reduce, not how to prevent.

Note that lack of a working example to prevent, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support of a preventive agent for skin cancer or a cutaneous tumor. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any drugs having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without ***undue experimentation***.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4, 9, 13, 17-20, 25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wei (US 5,824,702), as evidenced by Matsuura et al. (Journal of Food Science, 1989, Vol.54, No. 3, pp. 602-605) and Andrews et al. (Applied and Environmental Microbiology, 1979, Vol. 37, No. 3, pp. 559-566).

Wei teaches a method of inhibiting the harmful effect of UVR exposure to the human skin comprising topically applying a therapeutically effective amount of genistein to the skin at a

time close to UVR exposure to inhibit UVR-induced damage to the skin (abstract). Wei further teaches the genistein composition may be mixed with a variety of carriers and skin treatment compositions (abstract). The genistein composition is topically applied before, during or after exposure to UVR (column 2, lines 38-39). The genistein composition can be combined with compositions that have other cosmetic or medicinal properties such as skin creams, make-up preparations, and tanning lotions (column 2, lines 46-49). The concentration of genistein in the composition is 0.1-5 μmol genistein (column 6, line 7). Wei discloses in the prior art that genistein is a soybean isoflavone (column 1, line 42).

As evidenced by Matsuura et al., genistein is responsible for the objectionable flavor of soy milk (abstract). The concentration of genistein is increased during the soaking of soybeans, the first step of soy milk manufacturing (abstract).

As further evidenced by Andrews et al., there are a variety of soybean products such as soy flour, soy protein powder, and soy milk powder (abstract).

Regarding the amounts of the weight of the soy product in the composition, as recited in claims 1, 3, 9, 13, 17, 19, 25, and 29, it is noted that Wei teaches the concentration of genistein in the composition is 0.1-5 μmol genistein, which closely meets the weight of the soy product in the composition set forth in claims 1, 3, 9, 13, 17, 19, 25, and 29 (column 6, line 7). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the weight of the soy product provided in a composition, according to the guidance set forth in Wei, to provide a composition having desired weight of the soy product. It is noted that "[W]here the general conditions of a claim are disclosed in the prior

art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the application of the soy product, as recited in claims 2, 3, 18, and 19, it is noted that Wei teaches that the genistein composition is topically applied before, during or after exposure to UVR (column 2, lines 38-39). Thus it would be obvious that the topical application of the genistein composition may occur once daily on a continuous basis or for a duration of about four to about 10 weeks followed by on a daily basis thereafter.

Regarding the amounts of the weights of the emulsifier and preservative in the composition, as recited in claims 9, 13, 25, and 29, it is noted that Wei teaches skin creams and tanning lotions (column 2, lines 46-49). Since Wei teaches teaches skin creams and tanning lotions, it would be obvious that the genistein composition contain emulsifiers and preservatives in their appropriate amounts, which closely meets the weights of the emulsifier and preservative in the composition set forth in claims 9, 13, 25, and 29. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the weights of the emulsifier and preservative provided in a composition, according to the guidance set forth in Wei, to provide a composition having desired weight of the emulsifier and preservative in the composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 35 of copending Application Seiberg et al. (10/108,248).

Claim 35 of Seiberg et al. (10/108,248) is directed to a method of inhibiting the progression of a cutaneous tumor comprising topical application of a soybean trypsin inhibitor. It is obvious that a method for reducing the risk of disease is a form of inhibition of progression of that disease, a soybean trypsin inhibitor is a soy product, and skin cancer induced by ultraviolet radiation is a form of a tumor. Accordingly, claim 35 of Seiberg et al. (10/108,248) meet the limitation of the instant claims 1 and 17. Thus the method of inhibiting the progression of a cutaneous tumor comprising topical application of a soybean trypsin inhibitor is not patentable distinct between Seiberg et al. (10/108,248) and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

7. Claims 1 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 18, and 35 of copending Application Seiberg et al. (10/885,324) and claims 1, 18, and 35 of copending Application Seiberg et al. (11/100905).

Claims 1, 18, and 35 of Seiberg et al. (10/885,324) and claims 1, 18, and 35 of Seiberg et al. (11/100905) are directed to a method of inhibiting the progression of a cutaneous tumor, preventing the risk of skin cancer, and inhibiting the progression of a cutaneous tumor comprising topical administration of a soybean trypsin inhibitor. It is obvious that a method for reducing the risk of disease is a form of inhibition of progression of that disease, a soybean trypsin inhibitor is a soy product, and skin cancer induced by ultraviolet radiation is a form of tumor. Accordingly, claims 1, 18, and 35 of Seiberg et al. (10/885,324) and claims 1, 18, and 35 of Seiberg et al. (11/100905) meet the limitation of the instant claims 1 and 17. Thus the method of inhibiting the progression of a cutaneous tumor, preventing the risk of skin cancer, and inhibiting the progression of a cutaneous tumor comprising topical administration of a soybean trypsin inhibitor is not patentably distinct between Seiberg et al. (10/885,324), Seiberg et al. (11/100905), and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

8. Claims 1 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of copending Application Seiberg (11/549,813).

Claim 17 of Seiberg (11/549,813) is directed to a method treatment of radiation-induced skin damage to the skin using composition of a legume product. It is obvious treatment of a disease is a form of reducing the risk of that disease, radiation-induced skin damage can lead to cutaneous tumor development, ultraviolet radiation is a form of radiation, and soybeans are legumes. Accordingly, claim 17 of Seiberg (11/549,813) meet the limitation of the instant claims 1 and 17. Thus the method of treating mood disorder comprising administering pipamperone and venlaxafine is not patentably distinct between Buntinx (10/725,965) and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Wang

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